

PATENT
09/849,022
Docket 091/005

REMARKS/ARGUMENTS:

Applicants have canceled claims 1-36 without prejudice or disclaimer. Applicants reserve the right to reintroduce the subject matter of those claims at a later point in prosecution. Applicants added new claims 37 and 38. New claim 37 represents previous claim 15 written in independent form (i.e., incorporating previous claim 9 from which claim 15 depended). Claim 38¹⁴ is a rewrite of previously pending claim 26, but changed so that it depends on new claim 37 (thus also incorporating the limitations of previously pending claim 15). Claims 37 and 38 are now pending in this application. Reconsideration and allowance of the application is respectfully requested.

Double Patenting

The Office provisionally rejected claims 1-3, 6, 8, 9, 13, and 15-36 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over certain claims of copending U.S. Application Serial No. 11/010,140 ("the '140 application"). Action at page 3. The Office also provisionally rejected claims 1-3, 6, 8, 9, and 16-19 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over certain claims of copending U.S. Application Serial No. 10/141,220 ("the '220 application"). *Id.*

Applicants disagree with the Office's contentions of obviousness. However, because the rejections are provisional at this point, Applicants request that they be held in abeyance until the '140 or the '220 applications issue.

Rejection under 35 U.S.C. §112, first paragraph (enablement)

The Office rejected claims 1-3, 6, 8, 9, 13, and 15-36 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Action at page 4. Specifically, the Office argued that the claims must recite that the population of hES cells are "cultured in an environment containing both an extracellular matrix and fibroblast-conditioned medium" and that the promoter must be "an hES cell -specific promoter." *Id.* at page 5. Furthermore, the Office argued for claims 17-21, that the "instant claims provide no specific steps to arrive at populations of 50% hepatocytes or neural cells." *Id.* at page 8.

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Applicants respectfully traverse the rejection and disagree with the Office's arguments regarding lack of enablement. With respect to the issue of an extracellular matrix and fibroblast-conditioned medium, Applicants note that all currently pending claims recite those limitations. In addition, without acquiescence to the Office's contentions and solely to facilitate prosecution, Applicants have cancelled claims 17-21, making the Office's arguments regarding those claims moot.

The Office also asserted that the claims are not enabled because they "encompass utilizing promoters that are not expressed only in ES cells." Action at page 6. Applicants have no idea why there should be a requirement that the promoters within the claims only express in undifferentiated ES cells. While it is true the claims require that the promoters be expressed in the undifferentiated ES cells, it should not matter whether those promoters also are expressed in differentiated cells. Applicants point out that Example 6, which describes transfection of hES cells in feeder-free culture, involves the use of the CMV promoter, which is not a promoter whose expression is restricted to undifferentiated hES cells. Applicants request that the Office either better explain this basis for its rejections or withdraw that basis.

Rejection under 35 U.S.C. §112, second paragraph

The Office rejected claims 17-21 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Action at page 9. The Office pointed out that the term "composition" did not have an antecedent basis in the claim. Applicants amended claim 17 by deleting the term "composition" and inserting the term "population of hES cells", which does have antecedent basis in the claim. Applicant respectfully request that the Office reconsider and withdraw the rejection.

Rejection under 35 U.S.C. §103(a)

The Office rejected claims 1-3, 6, 8, 9, 16-18, 27, 28, 31, 32, and 33 as allegedly being obvious under 35 U.S.C. §103(a) over Reubinoff in view of Bodnar. Action at page 10.

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Applicants respectfully traverse the rejection and disagree with the Office's arguments regarding obviousness. However, Applicants have canceled claims 1-3, 6, 8, 9, 16-18, 27, 28, 31, 32, and 33. New claims 37 and 38 are derived from previously pending claims 15 and 26, and are thus not implicated in this rejection. Thus, the rejection is now moot.

The Office rejected claims 13, 22, 23, and 29 as allegedly being obvious under 35 U.S.C. §103(a) over Reubinoff in view of Bodnar and in further view of Capecchi. Action at page 12. Applicants respectfully traverse the rejection and disagree with the Office's arguments regarding obviousness. However, Applicants have canceled claims 13, 22, 23, and 29. Thus, the rejection is now moot.

The Office rejected claims 34, 35, and 36 as allegedly being obvious under 35 U.S.C. §103(a) over Reubinoff in view of Bodnar and in further view of Gerson. Action at page 14. Applicants respectfully traverse the rejection and disagree with the Office's arguments regarding obviousness. However, Applicants have canceled claims 34, 35, and 36. Thus, the rejection is now moot.

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Fees Due

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, Applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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June 13, 2006